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SUBJECT: PHARMA COMPANIES DISCUSS PORTUGAL MARKET ISSUES

Classified By: Gary B. Applegarth, Pol-Econ Officer, Reasons 1.4 (b) and (d).

#### SUMMARY

1. (C/NF) The Local American Working Group (LAWG) of the Pharmaceutical Association in Portugal hosted a September 24 breakfast meeting with diplomatic and company representatives to discuss strategies for addressing longstanding market access issues. Diplomatic participants opined that industry lobbying efforts would be more effective if presented jointly by the industry rather than by individual companies, stressing the potential benefits to the Portuguese economy of improving market access rather than the negative monetary impacts of existing regulatory issues to the pharmaceutical companies. The diplomatic participants also suggested the issue be addressed with the GOP via a joint working session including the ministries of Finance, Justice, Economy, and Health, to underscore industry recognition of the magnitude of the issues and facilitate comprehensive solutions. The industry representatives are improving their lobbying approach for seeking an improved business environment in Portugal, but the group faces a difficult task to improve market conditions through negotiations with a new minority government and a struggling economy. End summary.

#### INDUSTRY GROUP PRESENTS CHALLENGES, SEEKS EMBASSY GUIDANCE

2. (SBU) On September 24 the Charge d'Affaires, Senior Commercial Officer, and Poleconoff attended a roundtable breakfast meeting organized by the Local American Working Group (LAWG) of the Pharmaceutical Association in Portugal. Also in attendance were: UK Ambassador Ellis, Swiss Ambassador Shaller, German Econ Counselor Deichmann, and French Econ Counselor Monne. Company representatives included General Managers from Abbott Labs (U.S.), Amgen (U.S.), Bristol-Myers Squibb (U.S.) Janssen-Cilag (U.S.), Pfizer (U.S.), Merck Sharp & Dohme (U.S.), Schering-Plough (U.S.), AstraZeneca (U.K.), GlaxoSmithKline (U.K.), Bayer (Germany), Novartis (Switzerland), Roche (Switzerland), and Aventis (France).

3. (SBU) The LAWG called the meeting to discuss market access issues. In particular, they identified several "key priority" problems with the regulatory environment, including unstable pricing policies, GOP reimbursement delays, capricious and opaque revenue caps, and lax enforcement of patent rights. Although these problems have been repeatedly raised by industry in recent years, this was the first time that the LAWG sought to coordinate its messaging and strategy development with all diplomatic and industry players simultaneously, and is an approach post has urged them to develop.

4. (SBU) After a brief presentation summarizing the issues and noting the impact that they have had on the pharmaceutical industry in Portugal (the LAWG estimates lost

revenues of 540 million euros from 2006 to 2008), the LAWG members requested diplomatic input for effective ways to engage and lobby the GOP.

#### ACCENTUATE THE POSITIVE...

15. (SBU) All diplomatic representatives agreed that future dialogue with the GOP would be more effective if conducted jointly by industry representatives. The diplomatic attendees also suggested that Portuguese firms impacted by the same market issues, such as Bial, a major Portuguese pharmaceuticals manufacturer based in Porto, be included in the dialogue to demonstrate that these are not exclusively "foreign company" issues. U.K. Ambassador Ellis emphasized the need for LAWG members to link their recommendations to Portugal's innovation and technology goals when speaking with public officials and to stress the advantages of proposed reforms (e.g., increased industry investment in Portugal, job creation) rather than dwelling on corporate financial losses.

16. (SBU) Swiss Ambassador Shaller recommended that discussion with the GOP be held with all involved ministries at the table, including the Ministries of Finance, Justice, Economy, and Health, to highlight industry understanding of the broad impact of these issues and to facilitate a coordinated GOP response.

17. (SBU) Charge d'Affaires pointed out that, despite the purported transparency and predictability problems with Portugal's regulatory system, none of the LAWG members had left the market, which puts them in a precarious position when arguing to GOP officials that the current business

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climate is untenable. Charge d'Affaires recommended that dialogue with the GOP avoid an overemphasis on the intolerability of the status quo and instead, as Ambassador Ellis had said, focus on potential benefits to the Portuguese economy from policy and regulatory improvements.

18. (SBU) The French Econ Counselor suggested that industry leverage Portuguese partners where possible to increase the benefits to the Portuguese economy accrued by potential pharmaceutical industry investments.

#### AVOID REHASHING ACKNOWLEDGED RESOURCE CONSTRAINTS

19. (SBU) There were also several comments regarding the negative impact of resource and capability constraints on the regulatory environment in Portugal. Senior Commercial Officer related that the Ministry of Justice has blamed its slow performance in patent rights enforcement on a shortage of resources, and Poleconoff suggested that problems with data sharing among hospitals, researchers, and regulators in the Portuguese health care system are probably a factor in the GOP's difficulties with formulating realistic annual revenue caps for new drugs. Both cautioned against repeated industry complaints about GOP performance in these areas without offering realistic and achievable solutions.

110. (SBU) At the end of the meeting LAWG members expressed appreciation and committed to revising their "Key Priority" guiding document to reflect the input from the meeting. The LAWG members also asked to meet with the diplomatic representatives again soon to review their revisions before initiating direct dialogue with the GOP on these issues.

#### COMMENT

111. (C/NF) The LAWG session was productive, and a coordinated pharmaceutical industry approach to relevant GOP ministries has a better chance of succeeding than the uncoordinated overtures used before. It is ironic, however, that one of the major LAWG complaints is about the slow, uncoordinated, and non-responsive regulatory regime, given that we have been urging LAWG to change their lobbying

approach for over eighteen months. The group's leadership, reshuffled this year, seems to have taken our recommendations to heart and recognizes they have an opportunity to state their case to the new government. The LAWG has tentatively scheduled a follow-up meeting with diplomatic and industry representatives on November 10. Post will continue to support the LAWG's efforts and report future progress. End comment.

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